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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,901	06/18/2001	Carol H. Miao	58600-8250	1704

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EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

MAIL DATE DELIVERY MODE

08/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/884,901

Applicant(s)

MIAO ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on 31 May 2007.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-4, 15, 24, 36-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 15, 36-38 is/are allowed.
- 6)  Claim(s) 24 and 40-42 is/are rejected.
- 7)  Claim(s) 1-4, 24 and 40-42 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \*    c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- Interview Summary (PTO-413)  
Paper No(s)/Mail Date 5/22/2007.
- Notice of Informal Patent Application
- Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt and entry of the amendment dated 5/31/2007 is acknowledged. After entry of the amendment, claims 1-4, 15, 24, 36-38, and 40-42 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Objections***

Claims 1-4, 24 and 40-42 are objected to because of the following informalities: the claims recite a "human  $\alpha$ -1 antitrypsin promoter (SEQ ID NO: 5)". The use of parentheses introduces confusion as to whether the promoter must be SEQ ID NO: 5, or not. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

Claims 24 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. **This rejection is maintained for reasons made of record in the Office Action dated 1/31/2007, and for reasons set forth below.**

#### ***Response to Arguments***

Applicant's arguments filed 5/31/2007 have been fully considered but they are not persuasive. Applicants essentially assert that the specification discloses hepatic locus control elements ApoEHCR and ApoEHCR(s) (SEQ ID NOs: 4 and 9, respectively), and that each contains one copy of SEQ ID NO: 8.

However, claim 24 recites that the claimed cassette only comprises an "enhancer sequence consisting of SEQ ID NO: 8", and as such encompasses a broad genus of potential hepatic locus control elements that need only comprise a single copy of SEQ ID NO: 8. Thus, the claim scope encompasses expression cassettes wherein the hepatic locus control element consists of a single copy of SEQ ID NO: 8. Such an expression cassette is not disclosed in or

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contemplated by the specification. Furthermore, the claimed scope encompasses any and all nucleic acid sequences that might be considered a "hepatic locus control element" that have SEQ ID NO: 8 inserted at any location within the nucleic acid sequence. Again, such expression cassettes are not disclosed in or contemplated by the specification. All that is disclosed are vectors comprising four copies of SEQ ID NO: 8, and a hepatic locus control element having SEQ ID NO: 8 at a specific location within the element (i.e. SEQ ID NOs: 4 and 9). Furthermore, SEQ ID NO: 9 is merely a truncated version (the first 328 residues) of SEQ ID NO: 4 (771 residues). Thus, the disclosed examples of SEQ ID NO: 8 in an expression cassette do not provide support for the broadly claimed genus of expression cassettes comprising SEQ ID NO: 8, which encompasses any and all hepatic locus control element-like sequences that have SEQ ID NO: 8.

#### ***Response to Amendment***

The affidavit under 37 CFR 1.132 filed 5/31/2007 is found sufficient to overcome the 35 USC 103(a) rejection of claims 1-4 based upon being unpatentable over Snyder et al (U.S. Patent 6,936,243).

#### ***Conclusion***

Claims 15 and 36-38 are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart  
Examiner  
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SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER